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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,069	09/05/2003	David A. Hanson	6683.43USC1	8340
43541	7590	02/23/2006		
FAEGRE & BENSON ATTN: PATENT DOCKETING 2200 WELLS FARGO CENTER 90 SOUTH 7TH STREET MINNEAPOLIS, MN 55402-3901			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
DATE MAILED: 02/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/656,069	Applicant(s) HANSON ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38 and 40-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a continuation of application 09/896,926 filed on 6/28/2001, which is a continuation-in-part of 09/611,237 filed on 7/6/2000. The examiner has found the claims in this application to be directed to the additional material presented solely in the 09/896,926. Thus all claims have been examined in reference to a filing date of 6/28/2001.

Claim Rejections - 35 USC § 112

The previous rejections based upon 35 USC 112 first paragraph are now withdrawn due to applicant's claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 38, and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al (US Patent 6,083,225) in view of Hamada (US Patent 6,436,101).

Winslow et al disclose a "surgical retractor" (10), which could be used as a chisel due to its blades (20). It has a hollow inner cavity to which slot (16) interfaces. Column 3, lines 25-28 discuss how the cavity is intended to guide surgical instrumentation to the surgical site. Column 5, lines 53-58 discuss how the slots (16) can also permit lateral

Art Unit: 3733

introduction of spinal instrumentation. This final point would require instrumentation to include a radial protrusion in order to be handled by the surgeon. Winslow et al further disclose a two-piece implant (**s** and **200**) where **s** is a bone growth material and **200** is a support member.

Winslow et al fails to explicitly disclose the use of a rasp with the device (**10**), however it is well known in the art to utilize a rasp, rongeur, osteotome, and the like when preparing bone surfaces for implantation. Hamada discloses a rasp for use in spinal surgery (**501**) with a detachable head portion (**503**) connected by a pin (**131**) that limits the rotation of the head portion with respect to the handle (**105**). While the dimensions of the rasp are unknown in relation to the chisel of Winslow et al, it is normally within the skill of one of ordinary skill in the art to simply scale up or down a device as long as the means to do so existed at the time of invention. The motivation to allow sliding of Hamada's rasp within the guide of Winslow, et al includes limiting the area obscured to the surgeon during a procedure as well as controlling/guiding an instrument safely into the body, especially one as critical as the spine.

Hamada's rasp (**503**) as shown in **Figures 43 and 44** has rasping structures on the top (**507**) and bottom (**521**) surfaces. One of ordinary skill in the art would have also readily seen the need to interface with the rasp head to slide it back and forth while within the cavity (**16**) of Winslow et al. Thus, pin (**131**) or a handle structure that would insert through the slot (**16**) of Winslow et al to connect to the bore (**517**) of Hamada would have been a simple substitution of function. With the handle in place (e.g. **131**), it would also limit rotation of the rasp head within the hollow cavity of chisel (**10**). At this

Art Unit: 3733

orientation, the top blade of the chisel would pass over the top surface of the rasp and the bottom blade would pass below the bottom surface of the rasp.

It is inherent that the bone implant (s and **200**) be shaped to fit within the regions prepared by the rasp and chisel, else there is no point in preparing the site for implantation.

In regard to claims 44 and 45, applicant failed to disclose any criticality in using a c-shaped rasp head and c-shaped implant support. Examiner after reading the specification and analyzing the drawings has determined that the c-shape is solely a design choice. Applicant is using a c-shaped rasp that creates a circular removal of bone tissue with the support portion of the implant being inserted by the "c" opening. The bone graft material is then pushed in through the same opening. Hamada is using a circular rasp to also create a circular removal of bone tissue and implanting a subsequent circular support implant (**Figure 62**). The implant of Hamada has a bore (**757**) to accept bone graft material as well. One of ordinary skill in the art would have readily seen how the implants of Hamada and Winslow et al are interchangeable as they perform the same function.

The "c" opening of both the rasp and implant of applicant holds no patentable weight over Hamada because in both instances, applicant's device functions in the same way as Hamada. Creating a "c" opening in order to push an implant into position from the center is the same as pushing an implant by the side (as in Hamada).

Response to Arguments

Applicant's arguments filed January 17th, 2006 have been fully considered but they are not persuasive. Applicant asserts that Winslow lacks blades having cutting edges, and that reference character (20) would only distract two vertebral bodies. Applicant fails to recognize that between vertebral bodies are vertebral discs. These discs would be pierced by structure (20) and thus be "cut." Applicant has failed to provide enough details to prove that the structure disclosed by Winslow is incapable of performing the claimed functions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).


Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer

Richard Shaffer
February 13th, 2006


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER